UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF NEW YORK

UMB BANK, N.A., as Trustee, Plaintiff, v. SANOFI, Defendant.	:	Case No. 15 Civ. 8725 (GBD) (RWL) ECF CASE

MEMORANDUM OF LAW IN SUPPORT OF SANOFI'S MOTION FOR SUMMARY JUDGMENT ON COUNTS I, II, AND VII OF THE SECOND AMENDED COMPLAINT

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Sanofi respectfully submits this memorandum of law in support of its Motion for Summary Judgment on Counts I, II, and VII of the Second Amended Complaint (the "Motion").[1]

PRELIMINARY STATEMENT

Plaintiff UMB Bank, N.A. ("Plaintiff") purports to bring this action for the benefit of the holders of contingent value rights ("CVRs") that Sanofi issued in connection with its 2011 acquisition of Genzyme Corporation ("Genzyme"). The two companies agreed on the CVRs, which are registered with the U.S. Securities and Exchange Commission and publicly traded on the NASDAQ, as a means of bridging a valuation gap during their merger negotiations with respect to Genzyme's late-stage product pipeline. The CVRs offered holders potential payments conditioned on the achievement of certain developmental and sales-related milestones with respect to Lemtrada, a multiple sclerosis ("MS") drug, as well as the achievement of certain production targets with respect to both Cerezyme and Fabrazyme, two rare disease drugs.

Although the CVRs originally were issued by Sanofi as partial consideration for the Genzyme acquisition (shareholders received $74 in cash and one CVR per Genzyme share), the majority of the CVRs later changed hands in the secondary market and are now held, in substantial part, by hedge funds and other opportunistic investors (many of which are funding this lawsuit). These new investors, in two related actions, sued Sanofi under the federal securities laws claiming that CVR holders were misled regarding the prospects for achieving U.S. Food and Drug Administration (the "FDA") approval of Lemtrada by March 31, 2014 (as required to trigger the first Lemtrada-related milestone payment) because Sanofi and Genzyme, while expressing confidence to the market, failed to disclose certain contemporaneous feedback

[1] The Second Amended Complaint is referred to herein as the "Complaint" or "Compl." Citations to Sanofi's Local Rule 56.1 Statement in support of the Motion are referenced herein as "SOF ¶ __". "Venezia Decl. Ex. __" refers to the exhibits appended to the accompanying Declaration of Stefania D. Venezia, dated September 13, 2019, submitted in support of the Motion.

from the FDA that, the investors contended, painted a less optimistic picture. *See In re Sanofi Sec. Litig.*, 13 Civ. 8806 (PAE) (S.D.N.Y.), and *AG Funds, L.P. v. Sanofi*, 14 Civ. 2211 (PAE) (S.D.N.Y.). In a January 2015 decision, however, Judge Paul Engelmayer dismissed the cases in their entirety, rejecting the investors' version of events as "distend[ing]" the regulatory record, and holding that the claims were not only implausible, but "conjectural" and "purely speculative." *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 545 & n.15, 531, 548 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016).

Searching for another potential avenue of redress on behalf of the hedge funds and opportunistic investors who, in many cases, bought their CVRs for pennies on the dollar and were viewing their CVR investments primarily as a litigation play, Plaintiff (on behalf of the CVR holders) filed the instant action, which, among other things, asserts that Sanofi breached the contract governing the CVRs, referred to herein as the "CVR Agreement," by: (i) failing to use "Diligent Efforts," a defined term, to achieve the "Approval Milestone" (*i.e.*, FDA approval of Lemtrada by March 31, 2014) (Count I); (ii) failing to use "Diligent Efforts" to achieve "Product Sales Milestone #1" (or "PSM#1") (*i.e.*, $400 million in Lemtrada sales during a contractually-specified period) (Count II); and (iii) failing to use commercially reasonable efforts (undefined) to achieve the "Production Milestone" (*i.e.*, the production and "Release," also a defined term, of a contractually-specified quantity of both Cerezyme and Fabrazyme by December 31, 2011) (Count VII).[2]

Although Sanofi's "efforts," both in developing and commercializing Lemtrada, as well as in the production of Cerezyme and Fabrazyme, went well beyond what was contractually

[2] This Court has already determined that Plaintiff has not alleged and cannot allege a breach of contract claim with respect to "Product Sales Milestone #2-4," "as the deadline to meet those milestones is not until December 31, 2020." Mem. Decision & Order at 12 n.6, *UMB Bank, N.A. v. Sanofi*, 15 Civ 8725 (GBD) (S.D.N.Y. Sept. 8, 2016) [ECF No. 76].

required, whether Sanofi complied with its contractual "efforts" obligations need not be considered or decided in order to resolve this Motion. Rather, Sanofi is entitled to summary judgment on each of Counts I, II, and VII because Plaintiff cannot show, as it must under governing New York law, that a triable issue of fact exists as to whether Sanofi's alleged conduct *actually caused* any harm to Plaintiff (or to the CVR holders). Plaintiff's theory of causation and damages with respect to each of Counts I, II, and VII rests on an unprovable assertion: that had Sanofi not breached its "efforts" obligations under the CVR Agreement -- or, put another way, had Sanofi done things differently and (supposedly) better -- each of the Approval Milestone, PSM#1, and the Production Milestone would have been achieved.[3] But notwithstanding the millions of pages of documents that have been produced by Sanofi and various third parties, and the dozens of depositions of current and former Sanofi employees that have been taken, Plaintiff has not discovered a shred of evidence that *any* of the relevant milestones *actually* would have been met, instead filling that void with sheer conjecture, speculation, and hypothetical contrivances.

First, with respect to the Approval Milestone, Plaintiff has *no* evidence that, but for Sanofi's alleged conduct, the FDA -- a governmental regulatory agency over which Sanofi has no control -- would have approved Lemtrada by March 31, 2014. To the contrary, Plaintiff's own proposed regulatory expert, S. Albert Edwards, who spent just three years at the FDA roughly 40 years ago, cannot state that FDA approval would have occurred any earlier than it did, much less by a date prior to March 31, 2014. Nor does Plaintiff have any evidence that, had Sanofi taken any different action, the supposed "delays" in the regulatory timeline would have been avoided such that the FDA would have approved Lemtrada by March 31, 2014. *See* Point

[3] The Approval Milestone, PSM#1, and the Production Milestone were not achieved. Compl. ¶¶ 251, 255, 280; SOF ¶ 15.

II, *infra*.

Second, with respect to PSM#1, Plaintiff has *no* evidence that, but for Sanofi's alleged conduct, $400 million in Lemtrada sales would have been achieved during the requisite period. The *only* supposed "evidence" Plaintiff has on this score is a hypothetical U.S. sales model developed by Plaintiff's proposed U.S. commercialization expert, Steve Slovick. As explained below, however, Mr. Slovick's model is wholly speculative and, as such, cannot estimate with reasonable certainty, as it must, what Lemtrada's hypothetical sales would have been had Sanofi taken any different action (let alone that sales would have reached $400 million during the requisite period). *See* Point III, *infra*.

Third, with respect to the Production Milestone, Plaintiff has *no* evidence that, but for Sanofi's alleged conduct, the requisite additional quantities of *both* Cerezyme *and* Fabrazyme, two rare disease drugs manufactured through an extremely complex and highly regulated process, would have been produced and "Released" (as defined in the CVR Agreement) by December 31, 2011. The sum total of Plaintiff's supposed "evidence" in this regard is, once more, the speculation of experts regarding steps, including technical improvements, that Sanofi could have undertaken to improve and, in turn, expedite the process. But even these experts concede that the increased production that supposedly would have resulted from such steps, and whether such production would have been sufficient to achieve the Production Milestone, is nothing more than guesswork -- a woefully insufficient basis to allow the claim to proceed to trial. *See* Point IV, *infra*.

In sum, Plaintiff simply cannot satisfy its burden of coming forward with *actual evidence* of causation and damages, as necessary to demonstrate that it is entitled to a trial on its claims. The lack of such evidence is fatal, and summary judgment should therefore be granted in

Sanofi's favor on each of Counts I, II, and VII.

BACKGROUND

Sanofi respectfully refers the Court to its Local Rule 56.1 Statement, submitted in support of the Motion, and includes the undisputed background facts below solely for the Court's convenience.

A. The Parties

Plaintiff is a federally-chartered national banking organization with its principal place of business in Kansas City, Missouri, and is the "trustee of an express trust for the benefit of the [CVR] Holders." Compl. ¶¶ 9, 10.

Sanofi is a global pharmaceutical company organized under French law. *Id.* ¶ 11.

B. Sanofi's Acquisition of Genzyme

In February 2011, Sanofi and Genzyme entered into a definitive merger agreement pursuant to which Sanofi would acquire Genzyme for $74 in cash and one publicly traded CVR per Genzyme share. *See id.* ¶¶ 2-4. In the months preceding the announcement, the companies differed over the valuation of Genzyme's late-stage product pipeline, including Lemtrada, a new therapy for MS with the scientific name alemtuzumab. *Id.* Sanofi and Genzyme ultimately bridged their valuation gap with the CVRs, which entitled holders to potential payments -- up to a total of $14 per CVR -- in the event that certain milestones with respect to Lemtrada, Cerezyme, and Fabrazyme were achieved. *See id.* at ¶ 27.

Sanofi completed the acquisition in April 2011, with Genzyme surviving as a wholly-owned Sanofi subsidiary. *Id.* ¶¶ 3, 11.

C. The CVR Agreement

The terms of the CVRs are set forth in the Contingent Value Rights Agreement, by and between Sanofi and the predecessor trustee, American Stock Transfer & Trust Company, dated

as of March 30, 2011 (the "CVR Agreement"). *See id.* ¶ 4; Compl. Ex. A. The CVR Agreement is governed by New York law. *See* Compl. Ex. A at § 1.10.

1. The Milestones

As relevant to this action, under the CVR Agreement, CVR holders were entitled to payments *if and when* certain milestones -- namely, the Approval Milestone, PSM#1, and the Production Milestone -- were achieved. Compl. ¶ 27. As made clear in the CVR Agreement, achievement of these milestones was not guaranteed. Compl. Ex. A. at 15 (defining the "Termination Date" of the CVR Agreement as "the earlier of (a) December 31, 2020 and (b) the Payment Date for Product Sales Milestone #4").

The Approval Milestone, as defined in the CVR Agreement, means the receipt of FDA approval of Lemtrada for the treatment of MS on or before March 31, 2014. *See id.* at 2; Compl. ¶ 27(b). PSM#1, as defined in the CVR Agreement, means $400 million in qualifying sales of Lemtrada during a specified period. Compl. Ex. A at 11; Compl. ¶ 27(c). The Production Milestone, as defined in the CVR Agreement, refers to the production and "Release" (a defined term in the CVR Agreement) of 734,600 400 Unit Vial Equivalents ("VEs") of Cerezyme and 79,000 35mg VEs of Fabrazyme on or before December 31, 2011. Compl. Ex. A at 13-14; Compl. ¶ 27(a).

2. The "Efforts" Provisions

Under Section 7.10 of the CVR Agreement, Sanofi agreed to use "Diligent Efforts," a defined term in the CVR Agreement, to achieve the Approval Milestone and PSM#1. *See* Compl. Ex. A. at 4-5; *see also* Compl. ¶¶ 29-30. Also under Section 7.10 of the CVR Agreement, Sanofi agreed to use "commercially reasonable efforts" (undefined) to achieve the Production Milestone. Compl. Ex. A at 43; *see also* Compl. ¶ 31.

D. Summary of Plaintiff's Allegations

With respect to Count I, Plaintiff alleges that Sanofi breached the CVR Agreement's "Diligent Efforts" provision by, among other things, "fail[ing] to cause Genzyme to follow the recommendations of the FDA and customary industry practice with respect to obtaining timely regulatory approval of Lemtrada and fail[ing] to cause Genzyme to submit an adequate application for FDA approval of Lemtrada that addressed the FDA's repeated concerns," which, according to Plaintiff, led to the Approval Milestone not being achieved. Compl. ¶ 18(a). Plaintiff further alleges that Sanofi "failed to use such efforts and employ the resources normally used by companies in the pharmaceutical business to present and explain the design, execution, and results of the Lemtrada trials in the Application to the FDA such that the Application would be approved by the deadline for the Approval Milestone, and thus materially breached its obligations under the CVR Agreement." *Id.* ¶ 59; *see also id.* ¶¶ 43-94.

With respect to Count II, Plaintiff alleges that Sanofi breached the CVR Agreement's "Diligent Efforts" provision by, among other things, failing to "devote adequate resources to the promotion and commercialization of Lemtrada, including by failing to cause Genzyme to promote and commercialize Lemtrada in a manner normally used by other companies in the pharmaceutical business in the promotion of such a product." *Id.* ¶¶ 18(b), 96. Plaintiff further alleges that "[h]ad Sanofi taken actions normally used by companies in the pharmaceutical business to commercialize Lemtrada, including but not limited to, promoting Lemtrada, hiring and building out a sales force, providing sufficient information to physicians along with other relevant training, and making appropriate expenditures relating to the foregoing, sales during this period would have been significantly greater such that Sanofi would have achieved Product Sales Milestone #1 as early as the second quarter of 2015, but no later than the third quarter of 2015." *Id.* ¶¶ 98; *see also id.* ¶¶ 95-122.

With respect to Count VII, Plaintiff alleges that Sanofi breached the CVR Agreement's "commercially reasonable efforts" obligation to "achieve the Production Milestone on a timely basis." *Id.* ¶ 132. Plaintiff further alleges, among other things, that "Sanofi delayed implementing helpful manufacturing process improvements that were already in its possession and control," and "failed to provide necessary resources to facilitate production," which, according to Plaintiff, led to the failure to achieve the Production Milestone. *Id.* ¶ 132, *see also* ¶¶ 131-228.

ARGUMENT

A movant is entitled to summary judgment when there is "no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Although the Court must "examine the evidence in the light most favorable to the party opposing the motion," *Upper Deck Co., LLC v. BreaKey Int'l, BV*, 390 F. Supp. 2d 355, 358 (S.D.N.Y. 2005), the non-moving party cannot rely upon "'mere speculation or conjecture as to the true nature of the facts to overcome a motion for summary judgment'. . . . [It] must 'set forth specific facts showing that there is a genuine issue for trial.'" *In re Eugenia VI Venure Holdings, Ltd. Litig.*, 649 F. Supp. 2d 105, 116-17 (S.D.N.Y. 2008), *aff'd sub nom. Eugenia VI Venture Holdings, Ltd. v. Glaser*, 370 F. App'x 197 (2d Cir. 2010); *see also Maalouf v. Salomon Smith Barney, Inc.*, 2004 WL 2008848, at *4 (S.D.N.Y. Sept. 8, 2004), *aff'd sub nom. Maalouf v. Citigroup Global Mkts., Inc.*, 156 F. App'x 367 (2d Cir. 2005) ("the nonmoving party may not rely on conclusory allegations or unsubstantiated speculation"); *Virgin Atl. Airways Ltd. v. British Airways PLC*, 69 F. Supp. 2d 571, 579 (S.D.N.Y. 1999) ("a party may not rest . . . on conclusory or incomplete expert analyses [to defeat a motion for summary judgment] any more than it may rest on unsubstantiated allegations of its pleadings") (quoting *Ortho Diagnostic Sys.*

Inc. v. Abbott Labs., Inc., 920 F. Supp. 455, 471 (S.D.N.Y. 1996)), *aff'd sub nom. Virgin Atl. Airways Ltd. v. British Airways PLC*, 257 F.3d 256 (2d Cir. 2001).

Where, after discovery, and as here, "the nonmoving party fails to make a showing sufficient to establish the existence of an element essential to one of the claims, and on which that party will bear the burden of proof at trial, summary judgment should be granted." *Upper Deck*, 390 F. Supp. 2d at 358 (citations omitted); *see also, e.g.*, *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986) (summary judgment appropriate where moving party points to an "absence of evidence to support the nonmoving party's case").[4]

I. PLAINTIFF MUST ESTABLISH THAT THE RELEVANT MILESTONES WOULD HAVE BEEN ACHIEVED BUT FOR SANOFI'S ALLEGED CONDUCT

Under New York law, in order to recover on its breach of contract claims, Plaintiff is required to prove, by a preponderance of the evidence: (i) the existence of a contract; (ii) performance of its obligations under the contract; (iii) Sanofi's breach of the contract; and (iii) *damages* to Plaintiff "*caused by [Sanofi's] breach*." *Diesel Props. S.r.l. v. Greystone Bus. Credit II LLC,* 631 F.3d 42, 52 (2d Cir. 2011) (emphasis added); *see also, e.g.*, *Nat'l Mkt. Share, Inc. v. Sterling Nat'l Bank*, 392 F.3d 520, 525 (2d Cir. 2004) ("Causation is an essential element of damages in a breach of contract action."); *Acumen Re Mgmt. Corp. v. Gen. Sec. Nat'l Ins. Co.*, 2012 WL 3890128, at *10 (S.D.N.Y. Sept. 7, 2012) (Daniels, J.) (same).[5] To establish causation on its breach of contract claims, Plaintiff "must prove that [Sanofi's] breach directly and proximately caused [its] damages." *Nat'l Mkt. Share, Inc.*, 392 F.3d at 525 (citations omitted);

[4] Where there is a clear absence of evidence, there can be "no genuine issue as to any material fact" because a failure of proof of an essential element of a claim "necessarily renders all other facts immaterial." *Upper Deck*, 390 F. Supp. 2d at 358.

[5] Plaintiff cannot dispute that it must establish causation and damages, having stated in open court that "[i]f there is a breach proven, and that breach *causes* a milestone to have been missed, the contract says you get a dollar, or you get two dollars, or you get three dollars per CVR. . . ." May 14, 2019 Hearing Tr. at 9:10-14 (emphasis added).

see also, e.g., *Semi-Tech Litig., LLC v. Bankers Tr. Co.*, 353 F. Supp. 2d 460, 482 (S.D.N.Y. 2005) (causation "has two major components: cause-in-fact, or 'but-for' cause, and proximate cause"), *aff'd sub nom. In re Bankers Tr. Co.*, 450 F.3d 121 (2d Cir. 2006).[6]

Where the moving party "argues that there is insufficient evidence of causation, an issue on which the plaintiff would have the burden of proof at trial . . . [the burden shifts to the non-movant] to come forward with *evidence of actual causation and not just conjecture*." *Semi-Tech Litig.*, 353 F. Supp. 2d at 484 (emphasis added); *see also, e.g.*, *Acumen*, 2012 WL 3890128, at *10 ("a plaintiff must prove that a defendant's breach directly and proximately caused his or her damages"; "[d]amages . . . must be not merely speculative, possible, and imaginary, but they must be *reasonably* certain. . . ."). In other words, Plaintiff must prove -- with *actual evidence*, and *not* merely assumptions based on hindsight and wishful thinking -- that: (i) as to Count I, the FDA *would have approved* Lemtrada on or before March 31, 2014 *but for* Sanofi's alleged conduct; (ii) as to Count II, that Lemtrada qualifying sales *would have reached* at least $400 million *but for* Sanofi's alleged conduct; and (iii) as to Count VII, that 734,600 400 Unit VEs of Cerezyme and 79,000 35-mg VEs of Fabrazyme w*ould have been produced and Released* on or before December 31, 2011 *but for* Sanofi's alleged conduct.

In response to this Motion, Plaintiff likely will cherry-pick a selection of emails and other documents out of the millions of pages produced in this litigation in an effort to cast aspersions against Sanofi for its development and commercialization of Lemtrada, as well as its production of Cerezyme and Fabrazyme. The issue for this Motion, however, is *not* whether Sanofi used the

[6] "[I]n the usual case, it is undisputed that the complained-of loss would not have occurred had the defendant not committed the relevant breach. The only question is how far down the causal chain to go before cutting off liability. This is the proximate cause inquiry, and because it turns on such inherently factual questions as foreseeability, it usually is a question for the jury. Sometimes, however, what is at issue is but-for causation. This is such a case." *Semi-Tech Litig.*, 353 F. Supp. 2d at 482-83.

requisite "efforts" (which it did). Rather, the *only* (albeit dispositive) question before the Court is whether, even assuming, *arguendo*, that Sanofi did not comply with its "efforts" obligations, Plaintiff can establish, as it must, that each of the relevant milestones would have been achieved.[7] As to this question, and as set forth in more detail below, the record is devoid of evidence supporting Plaintiff's theory of causation and damages, and, as a result, summary judgment should be granted on each of Counts I, II, and VII. *See, e.g.*, *Semi-Tech Litig.*, 353 F. Supp. 2d at 486-87 (finding that "plaintiff has failed to meet its burden with respect to evidence of causation" and, thus, was not "entitled to have a jury fill that gap by speculating as to how [plaintiff] might have behaved if [defendant] had acted differently"); *see also Upper Deck*, 390 F. Supp. 2d at 359-62 (dismissing plaintiff's claim for hypothetical lost royalties because plaintiff's expert failed to show "with reasonable certainty" that defendant, under the circumstances, would have achieved the level of sales sufficient to trigger plaintiff's royalty payment); *Franconero v. Universal Music Corp.*, 2011 WL 566794, at *4-6 (S.D.N.Y. Feb. 11, 2011) (granting summary judgment for defendant record label on plaintiff singer's claim for album royalties where expert testimony asserting that singer's full-album sales declined because of record label's conduct consisted of "conclusory statements" that were insufficient to establish causation and damages with the requisite certainty), *aff'd sub nom. Franconero v. UMG Recordings, Inc.*, 542 F. App'x 14 (2d Cir. 2013).[8]

[7] *See, e.g., Acumen*, 2012 WL 3890128, at *11 (noting that "evidence of breaching conduct by Defendant does not establish that Plaintiff suffered actual damages").

[8] Because Plaintiff cannot establish that Sanofi's alleged conduct was the cause of any damages, any recovery for any breach by Sanofi of its obligations under the CVR Agreement, at best, would be limited to nominal damages. *See, e.g.*, *Maalouf*, 2004 WL 2008848, at *5 (holding that plaintiff's claims for damages were "entirely speculative" and limiting recovery "to nominal damages for [defendant's] alleged breach" in the amount of one dollar) (citations omitted).

II. PLAINTIFF CANNOT ESTABLISH THAT, BUT FOR SANOFI'S ALLEGED CONDUCT, THE APPROVAL MILESTONE WOULD HAVE BEEN ACHIEVED

In Count I, Plaintiff claims that, "[a]s a result of Sanofi's [failure to use Diligent Efforts to obtain FDA approval of Lemtrada by March 31, 2014,] the Approval Milestone was not met." Compl. ¶ 251. According to Plaintiff, with respect to Count I, Sanofi owes damages to Plaintiff in the amount of $1 per CVR. *Id*. at p. 68, ¶ A. In order to recover on Count I, and assuming solely for the purposes of this Motion that Plaintiff can establish the predicate failure by Sanofi to use "Diligent Efforts," Plaintiff must prove that *but for* Sanofi's alleged conduct, the FDA would have approved Lemtrada by March 31, 2014. Plaintiff cannot.

First, Plaintiff has *no* evidence -- as opposed to speculation and conjecture based entirely on hindsight -- that, had Sanofi used what Plaintiff believes would have been Diligent Efforts, the FDA, a governmental regulatory agency over which Sanofi has no control, would have approved Lemtrada by March 31, 2014. Second, Plaintiff has *no* evidence that Sanofi could have avoided various purported "delays" in the Lemtrada application timeline such that the FDA, had such "delays" not occurred, would have been in a position to approve Lemtrada by March 31, 2014. As a result, there is simply no basis for the trier of fact to conclude, as required for Plaintiff to recover on Count I, that the Approval Milestone would have been achieved had Sanofi acted any differently. Summary judgment on Count I should therefore be granted in Sanofi's favor.

A. Plaintiff Has No Evidence That The FDA Would Have Approved Lemtrada by March 31, 2014 Had Sanofi Acted Any Differently

The FDA, a governmental regulatory agency over which Sanofi has no control, has the ultimate authority and discretion over the approval of, among other things, drugs in the U.S. SOF ¶ 16. Thus, irrespective of Sanofi's efforts, the FDA had the ultimate power to approve -- or not approve -- Lemtrada in the U.S. As a result, in order to recover on its claim, Plaintiff must

come forward with *actual evidence* that, but for Sanofi's alleged failure to use what Plaintiff believes would have been Diligent Efforts, the FDA would have approved Lemtrada by March 31, 2014. Plaintiff has no such evidence and its theory is nothing more than a case study in speculation.

Multiple cases have recognized the inherent uncertainty of governmental action and the resulting inability to prove causation and damages based thereon. For example, in *US Ecology, Inc. v. State of California*, 129 Cal. App. 4th 887, 910 (Cal. Ct. App. 2005), the California Fourth District Court of Appeal affirmed the trial court's finding of lack of causation with respect to plaintiff's promissory estoppel claim because it was "not reasonably certain that the federal government would have [acted] had defendants continued to use their 'best efforts.'" As explained by the *US Ecology* court:

> The evidence does not support the conclusion it was likely that the federal government would have transferred the property if requested to do so by the Davis administration. Any such outcome was speculative at best. Indeed, as the court found, it was no longer reasonable for Ecology to expend monies in reliance on defendants' promise to use their best efforts to obtain the Ward Valley property as of 1997, because actions by the Clinton administration made clear that the DOI's position would be a substantial obstacle to the transfer of the property irrespective of the State's efforts.

Id. at 910. Similarly, in *Integrated Waste Services, Inc. v. Akzo Nobel Salt, Inc.*, 921 F. Supp. 1037 (W.D.N.Y. 1996), *aff'd in part and rev'd in part*, 113 F.3d 296 (2d Cir. 1997), the court found that plaintiffs failed to establish damages with respect to the mine cavities at issue because "the relevant New York State authorities, such as the Department of Environmental Conservation . . . might not have given the project the necessary permits to proceed." *Id.* at 1043. Under those circumstances, "the evidence [wa]s simply too sparse, and the contingencies too remote to allow any reliable resolution of these issues. So many inferences would have to be drawn, upon so little evidence, that a damage award would be based on pure speculation." *Id.*;

see also In re Mirena IUD Prods. Liab. Litig., 169 F. Supp. 3d 396, 466-67 (S.D.N.Y. 2016) (precluding an expert from testifying "as to what type of label the FDA would or would not have ultimately accepted or rejected" as "impermissible speculation as to the state of mind of the FDA"); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) (excluding expert testimony "on the intent, motives or states of mind of corporations, regulatory agencies and others" as "hav[ing] no basis in any relevant body of knowledge or expertise").[9]

The same holds true here. Plaintiff relies exclusively on pure conjecture and speculation from its proposed regulatory expert, Mr. Edwards, who, [redacted] Venezia Decl. Ex. A at ¶ 114 (Edwards Rep.), subsequently admitted during his deposition that: (i) even a company exercising diligent efforts is at the mercy of the FDA when it comes to product approval; and (ii) he could not possibly state that FDA approval would have occurred at any particular time:

> Q. If you have a product where the regulatory strategy that's been employed is one that you would say is consistent with a diligent efforts obligation, but the product safety profile is such that the FDA is not willing to issue an approval, isn't that also the case, in other words, isn't it the case that you could have an impeccable regulatory strategy, yet the FDA still deems the product not suitable for public use?
>
> A. Yes, that can happen.

See Venezia Decl. Ex. B at 181:18-25, 182:2-4 (Edwards Tr.); *see also id.* at 261:17-19, 21-22 ("Q. Right, we did speak about that, but you can't actually guarantee that approval would have occurred; correct? . . . A. I can't guarantee that [FDA] approval would have occurred at that time."); *see also Vargas v. Transeau*, 514 F. Supp. 2d 439, 445 (S.D.N.Y. 2007) ("[t]he

[9] At the appropriate time, Sanofi intends to file *Daubert* motions.

testimony of an expert who equivocates" -- as Mr. Edwards does here -- "need not be credited by the Court in resolving a motion for summary judgment"), *aff'd sub nom. Vargas v. Pfizer, Inc.*, 352 F. App'x 458 (2d Cir. 2009); *Lippe v. Bairnco Corp.*, 288 B.R. 678, 686 (S.D.N.Y. 2003) (holding that "expert testimony should be excluded if it is 'speculative or conjectural'"), *aff'd* 99 F. App'x 274 (2d Cir. 2004).[10]

In short, there is not a shred of evidence in the record that the FDA would have approved Lemtrada by March 31, 2014 but for Sanofi's alleged conduct.[11] Plaintiff, therefore, cannot establish causation and damages with respect to the Approval Milestone.

B. Plaintiff Has No Evidence That The Supposed "Delays" In The Application Timeline Would Have Been Avoided Had Sanofi Done Anything Differently

The Court need not go any further to grant summary judgment in Sanofi's favor on Count I, as the dearth of evidence that the FDA would have approved Lemtrada by March 31, 2014 under some alternate factual scenario is fatal to such claim. Nevertheless, Count I fails for an additional and independent reason: Plaintiff has focused on what it describes as "delays" in the application timeline, but it likewise has no evidence establishing that Sanofi could have avoided the various supposed "delays" in the application timeline such that the FDA would have been in a position to approve Lemtrada by March 31, 2014. In other words, beyond Plaintiff's inability to prove how a government agency would have acted in some alternate universe, Count I fails because Plaintiff also needs to (but cannot) show that any of the supposed "delays" in the application timeline would not have occurred had Sanofi done anything differently. Plaintiff has

[10] In fact, Mr. Edwards admitted that his conclusion regarding the time period during which the FDA would have approved Lemtrada had Sanofi used what Plaintiff believes would have been Diligent Efforts was based entirely on a series of unsupportable assumptions. Venezia Decl. Ex. B at 229:6-9 (Edwards Tr.) ("Q. So based on all of those *assumptions* that you just listed, that's how you reached your third or fourth quarter of 2013? A. Right, that's my explanation.") (emphasis added).

[11] That the FDA approved Lemtrada in November 2014 based on the same underlying clinical trial data is not evidence that the FDA would have approved Lemtrada by March 2014 if Sanofi had, as Plaintiff alleges, used what Plaintiff believes would have been Diligent Efforts. *See infra* pp. 18-19.

no evidence to make that showing. There are simply too many assumptions and contingencies in Plaintiff's theory of causation to support a non-speculative damages award. *See, e.g.*, *US Ecology, Inc.*, 129 Cal. App. 4th at 910; *Integrated Waste*, 921 F. Supp. at 1043; *see also, e.g.*, *Upper Deck*, 390 F. Supp. 2d at 359-62; *Semi-Tech Litig.*, 353 F. Supp. 2d at 486-87; *Franconero*, 2011 WL 566794 at *4-6.

It is undisputed that the FDA finally approved Lemtrada on November 14, 2014. SOF ¶ 20. Mr. Edwards, however, contends that [redacted]. Venezia Decl. Ex. A at ¶¶ 95-96, 114 (Edwards Rep.). As explained below, Plaintiff has no *actual evidence* -- as opposed to, again, conjecture and wishful thinking -- that *any* of these supposed "delays" could have been avoided had Sanofi done anything differently. Summary judgment can and should be granted on this basis as well.

1. Plaintiff has no evidence that Sanofi could have "anticipated" and avoided the supposed "delay" resulting from the pre-BLA meeting request

Mr. Edwards contends that [redacted]. Venezia Decl. Ex. A at ¶ 95 (Edwards Rep.). There is not a shred of evidence, however, supporting this assertion. Indeed, Mr. Edwards admitted during his deposition that: (i) pharmaceutical companies cannot always anticipate every request from the FDA; and (ii) he has never actually attended a pre-BLA

meeting. *See, e.g.*, Venezia Decl. Ex. B at 233:23-25, 234:2-7 (Edwards Tr.). Mr. Edwards also was unable to identify any pharmaceutical company that went to a pre-BLA meeting with the FDA without receiving any post-meeting follow-up, as was the case here. *Id.* at 235:19-23.[12] And, to state the obvious, Mr. Edwards had absolutely no involvement with the actual Lemtrada application. *Id.* at 46:14-17. In short, "[a]n expert's opinion is not a substitute for a plaintiff's obligation to provide evidence of facts. . . ." *Upper Deck*, 390 F. Supp. 2d at 361.

2. Plaintiff has no evidence that Sanofi could have avoided the RTF and the supposed resulting "delay"

Mr. Edwards next contends that [redacted]. Venezia Decl. Ex. A at ¶¶ 96, 104 (Edwards Rep.). Again, the *only* supposed "evidence" on this point is Mr. Edwards' say-so, which cannot suffice. *See Nimely v. City of New York*, 414 F.3d 381, 396 (2d Cir. 2005) ("a district court [is not required] to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert") (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). There is not a shred of factual support that the FDA would not have issued the RTF had Sanofi done anything differently. Indeed, Mr. Edwards admitted during his deposition that, upon reviewing the Lemtrada application, and notwithstanding any prior concerns or issues that the FDA might have flagged for Sanofi, the FDA nonetheless could have identified new or additional concerns leading it to issue the RTF. Venezia Decl. Ex. B at 214:6-16 (Edwards Tr.). Thus, the notion that the FDA would have done anything other than what it did is "speculative at best." *US Ecology*, 129 Cal. App. 4th at 910; *see also Mirena*, 169 F. Supp. 3d at 466-67 (excluding expert testimony on what the FDA

[12] *See Davis v. Carroll*, 937 F. Supp. 2d 390, 419 (S.D.N.Y. 2013) (excluding expert testimony where, among other things, the expert made a number of factual assertions in his report for which the expert "was unable to muster even one example of business being conducted in this manner").

"would or would not have ultimately accepted or rejected" as "impermissible speculation as to the state of mind of the FDA"); *Rezulin*, 309 F. Supp. 2d at 546 (excluding expert testimony "on the intent, motives or states of mind of corporations, regulatory agencies and others" as "hav[ing] no basis in any relevant body of knowledge or expertise").

3. Plaintiff has no evidence that Sanofi could have avoided the CRL and the supposed resulting "delay"

Finally, Mr. Edwards contends that [redacted] Venezia Decl. Ex. A at ¶ 114 (Edwards Rep.). Missing from the evidentiary record, however, is any *actual evidence* -- as opposed to more conjecture based on hindsight -- showing that, had Sanofi taken any or all of these actions, the FDA would have approved Lemtrada by March 31, 2014.

[redacted]. Venezia Decl. Ex. A at ¶ 127 (Edwards Rep.); *see also* Venezia Decl. Ex. C at ¶ 123 (Chin Rep.). Neither Mr. Edwards nor Dr. Chin knows why the FDA chose to act when it did, nor can they (or anyone else) predict when or how FDA approval otherwise might have occurred. *See Mirena*, 169 F. Supp. 3d at 466-67 (excluding expert testimony on what the FDA "would or would not have ultimately accepted or rejected" as "impermissible speculation as to the state of mind of the FDA"); *Rezulin*, 309 F. Supp. 2d at 546 (similar). Simply put, there is zero evidence that the FDA would have approved

Lemtrada any earlier based on the same underlying data had Sanofi taken one or more of the additional actions outlined by Plaintiff's experts.

Rather, the evidence illustrates just how speculative Plaintiff's theory is: (i) Dr. Chin admitted that addressing potential sources of bias might still fail to sufficiently persuade the FDA (Venezia Decl. Ex. D at 254:22-254:25) (Chin Tr.); (ii) Mr. Edwards admitted that he could not say with any certainty that the mere commitment to conduct additional clinical trials would have caused the FDA to act any differently (Venezia Decl. Ex. B at 278:22-23, 279:3-4) (Edwards Tr.);[13] and (iii) Mr. Edwards and Dr. Chin both admitted that they could not be certain that the FDA would have acted any differently if Sanofi had actually commenced any additional clinical trials, at best noting that such action "might" have made a difference. Venezia Decl. Ex. B at 271:16-19, 275:20-23, 275:25-276:2 (Edwards Tr.); Venezia Decl. Ex. D at 317:24-318:1, 318:3-8 (Chin Tr.).

* * *

In sum, Plaintiff's theory of causation and damages with respect to Count I is built entirely upon the unprovable assumption that the FDA would have taken a different course of action and actually approved Lemtrada by March 31, 2014 had Sanofi simply used what Plaintiff believes would have been Diligent Efforts. But the law is clear: speculative and conclusory statements are insufficient to establish the requisite causal connection. *See, e.g.*, *US Ecology*, 129 Cal. App. 4th at 910 (evidence did not show that it was "reasonably certain" that using contractually required "best efforts" would have caused the federal government to have acted differently); *Integrated Waste Servs., Inc.*, 921 F. Supp. at 1043 (because "the evidence is simply

[13] Mr. Edwards also admitted that although he "hope[d]" that additional clinical trials would be completed in sufficient time to achieve FDA approval before March 31, 2014, he had not "delved into the specific step-by-step process to tease that out." *Id.* at 270:21-271:4 (Edwards Tr.).

too sparse, and the contingencies too remote," any damage award "would be based on pure speculation"); *Virgin*, 69 F. Supp. 2d at 579 (holding that "[w]hen an expert opinion is not supported by sufficient facts to validate it in the eyes of the law . . . it cannot support a jury's verdict") (citation omitted); *see also Mirena*, 169 F. Supp. 3d at 466-67 (excluding expert testimony on what the FDA "would or would not have ultimately accepted or rejected" as "impermissible speculation as to the state of mind of the FDA"); *Rezulin.*, 309 F. Supp. 2d at 546 (excluding expert testimony "on the intent, motives or states of mind of . . . regulatory agencies . . ." as "hav[ing] no basis in any relevant body of knowledge or expertise"); *Lippe*, 288 B.R. at 686 (holding that "expert testimony should be excluded if it is 'speculative or conjectural'"). Allowing Plaintiff to present this theory at trial would thus be improper. *See, e.g.*, *Semi-Tech Litig.*, 353 F. Supp. 2d at 486 (finding that plaintiff was not "entitled to have a jury fill [the evidentiary] gap by speculating as to how [plaintiff] might have behaved if [defendant] had acted differently"). Accordingly, summary judgment should be granted on Count I.

III. PLAINTIFF CANNOT ESTABLISH THAT, BUT FOR SANOFI'S ALLEGED CONDUCT, PSM#1 WOULD HAVE BEEN ACHIEVED

In Count II, Plaintiff claims that, "[a]s a result of Sanofi's [failure to use Diligent Efforts]," PSM#1 was not met. Compl. ¶ 255. According to Plaintiff, Sanofi owes damages to Plaintiff in the amount of $2 per CVR. *Id.* at ¶ 27(c). In order to recover on Count II, and assuming solely for the purposes of this Motion that Plaintiff can establish the predicate failure by Sanofi to use Diligent Efforts, Plaintiff must establish that, *but for* Sanofi's alleged conduct, Sanofi would have achieved $400 million in qualifying Lemtrada sales. Once again, Plaintiff cannot.

As an initial matter: (i) [redacted]

[redacted] (Venezia Decl. Ex. E at ¶ 166 (Blum Rep.)); and (ii) Dr. Manfred Caeser, Plaintiff's proposed non-U.S. commercialization expert, offers no opinion (nor does he plan to) regarding what non-U.S. sales of Lemtrada would have been had Sanofi used what Plaintiff believes would have been Diligent Efforts. Venezia Decl. Ex. F at 70:24-71:6 (Caeser Tr.). As a result, the *only* supposed "evidence" Plaintiff can proffer to even attempt to show hypothetical Lemtrada sales sufficient to achieve PSM#1 is the report and testimony of its proposed U.S. commercialization expert, Mr. Slovick, and, specifically, his hypothetical U.S. sales model (the "Slovick Sales Model"). The Slovick Sales Model, however, is woefully deficient and cannot possibly establish causation and damages with the requisite certainty needed for Plaintiff to recover with respect to PSM#1.

A. Damages Based On Projections Of Sales Must Be Reasonably Certain

It is well-settled that, when projecting sales for the purpose of calculating damages, the party seeking damages cannot merely rely on unsupported (or unsupportable) assumptions. *Upper Deck* is directly on point in this regard. There, Plaintiff BreaKey asserted that its contractual counterparty, Defendant Upper Deck, breached a royalty agreement by, among other things, failing to "launch the product in reasonable commercial quantities," and sought to recover on its contractual right to a ten percent royalty on annual sales in excess of $25 million. *Upper Deck*, 390 F. Supp. 2d at 357. On summary judgment, the Court held that BreaKey was obligated to "come forward with evidence sufficient to demonstrate *with reasonably certainty* that Upper Deck would have generated sales in excess of $25 million annually during the term of the agreement." *Id.* at 358 (emphasis added). BreaKey sought to satisfy this burden with expert testimony on the hypothetical level of sales that would have been generated had Upper Deck fully performed its obligations. *Id.* The Court held that the expert opinion was insufficient to

defeat summary judgment because the expert's "calculations [we]re based on too many unsupportable assumptions to establish the existence of lost royalties with the reasonable certainty required." *Id.* at 360. Among other things, the Court recognized that the product at issue (like Lemtrada) was new and, as a result, there was "an insufficient historical record upon which to project future earnings." *Id.* Accordingly, the Court granted Upper Deck's motion for summary judgment on BreaKey's claim for lost royalties based on hypothetical sales. *Id.* at 362.

Franconero is also instructive. There, the Court granted summary judgment to the defendant record label on the plaintiff singer's claim for album royalties. *Franconero*, 2011 WL 566794, at *7. The Court concluded that an expert affidavit asserting that the singer's full-album sales declined because of the record label's conduct consisted of "conclusory statements" insufficient to establish causation with the requisite certainty, as the singer provided no evidence showing that, but for the defendant's conduct, "consumers who purchased compilation albums would otherwise have purchased Plaintiff's full-length albums." *Id.* at *5; *see also Holland Loader Co., LLC v. FLSmidth A/S*, 313 F. Supp. 3d 447, 481 (S.D.N.Y. 2018) (holding following a bench trial that plaintiff "must provide a 'stable foundation for a reasonable estimate' of lost profits or the claim 'fails for uncertainty'"), *aff'd* 769 F. App'x 40 (2d Cir. 2019); *Celebrity Cruises Inc. v. Essef Corp.*, 434 F. Supp. 2d 169, 181-87 (S.D.N.Y. 2006) (excluding the expert testimony of several proposed damages experts because of, among other things, the experts' failure to justify the purported assumptions used and their reliance on unrealistic projections); *Point Prods. A.G. v. Sony Music Entm't, Inc.*, 2004 WL 345551, at *7 (S.D.N.Y. Feb. 23, 2004) (excluding proposed expert testimony regarding projected sales where the expert failed to account for "real world facts and events" and instead "adopt[ed] possibly speculative assumptions and predictions").

Here, Plaintiff relies on the Slovick Sales Model [redacted]. Venezia Decl. Ex. G at ¶ 209 (Slovick Rep.).[14] As discussed in more detail below, however, the Slovick Sales Model suffers from the very flaws identified in *Upper Deck* and similar cases and comes nowhere close to establishing -- with the requisite *reasonable certainty* -- that, *but for* Sanofi's alleged conduct, PSM#1 would have been achieved.

B. The Slovick Sales Model Fails To Provide Reasonable Certainty That, But For Sanofi's Alleged Conduct, PSM#1 Would Have Been Achieved

According to Mr. Slovick, his model [redacted] Venezia Decl. Ex. G at ¶ 221 (Slovick Rep.). As Mr. Slovick further explained during his deposition, the model was built using "secondary information, both external as well as internal to Sanofi Genzyme," and "assumptions that [he believed] were the most likely and supportable" to forecast Lemtrada sales. Venezia Decl. Ex. H at 412:15-21 (Slovick Tr.); *see also* Venezia Decl. Ex. G at ¶ 224 (Slovick Rep.).[15] Mr. Slovick's baseline assumptions, however, are far from "supportable." They are hypothetical, speculative, and not buttressed by *any* factual support in the record itself. For example:

- ***U.S. Launch Date for Lemtrada***. The CVR Agreement provides that Lemtrada sales begin to qualify for purposes of PSM#1 upon the "First Commercial Sale" in the relevant market, as defined in the CVR Agreement. Compl. Ex. A at 6. Mr. Slovick assumes a U.S. "First Commercial Sale" date of January 1, 2015 because "that's when we [*i.e.*, Mr. Slovick and his team] believe it *should have* launched."

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[14] [redacted] Venezia Decl. Ex. G at ¶¶ 234-57 (Slovick Rep.).

[15] Mr. Slovick admitted during his deposition that this was the *first instance* in which he modeled sales in this manner. Venezia Decl. Ex. H at 414:16-22 (Slovick Tr.).

Venezia Decl. Ex. H at 431:17-18 (Slovick Tr.) (emphasis added).[16] But Mr. Slovick nowhere establishes that had Sanofi used what Plaintiff believes would have been Diligent Efforts, First Commercial Sale in the U.S. would have occurred on January 1, 2015 (as opposed to some other date). Rather, Mr. Slovick simply picked a date that suited his opinion (*i.e.*, [redacted] (Venezia Decl. Ex. G at ¶ 91 (Slovick Rep.)). This assumption, therefore, is unreliable. *See Lava Trading, Inc. v. Hartford Fire Ins. Co.*, 2005 WL 4684238, *17 (S.D.N.Y. April 11, 2005) (excluding proposed expert testimony and holding that a "putative expert who seeks to estimate 'but for' sales cannot rely on his 'industry experience' or its equivalent as a substitute for a methodology that looks to specific data and proceeds to make statistically or scientifically valid inferences from the data"; "[i]ntuition won't do"); *Celebrity*, 434 F. Supp. 2d at 181-86 (excluding the expert testimony of several proposed damages experts because of, among other things, the experts' failure to justify the purported assumptions used); *Point Prods.*, 2004 WL 345551 at *7 (excluding proposed expert testimony regarding projected sales where the expert failed to account for "real world facts and events" and, instead, "adopt[ed] possibly speculative assumptions and predictions").

- ***Size of the Market (Number of Patients)***. Lemtrada was approved by the FDA as a disease modifying therapy for individuals with relapsing remitting multiple sclerosis ("RRMS"). SOF ¶ 20. Mr. Slovick nevertheless assumes [redacted] Venezia Decl. Ex. G at ¶ 237 (Slovick Rep.). However, there is no evidence in the record that [redacted] *See Virgin*, 69 F. Supp. 2d at 579 ("expert testimony without . . . a factual foundation cannot defeat a motion for summary judgment"); *see also Mirena*, 169 F. Supp. 3d at 466-67 (excluding expert testimony on what the FDA "would or would not have ultimately accepted or rejected" as "impermissible speculation as to the state of mind of the FDA").

- ***The Weighed-Average-Cost ("WAC") Price***. [redacted] Venezia Decl. Ex. G at ¶ 181 (Slovick Rep.). [redacted]

[16] The actual date on which the First Commercial Sale took place with respect to Lemtrada is irrelevant for purposes of this Motion. The point is simply that Mr. Slovick has no basis for the date he chose (for hypothetical U.S. qualifying sales), which forms one of the critical assumptions of his model.

[redacted] Venezia Decl. Ex. G at ¶ 236 (Slovick Rep.). Again, there is no evidence that Lemtrada revenues would have been maximized at [redacted] Nothing in "Sanofi's internal market research" indicates that a price of [redacted] was the revenue-maximizing price, and Mr. Slovick cites no further support for this assumption. Venezia Decl. Ex. H at 420:4-11 (Slovick Tr.). As a result, Mr. Slovick's assumption is flawed and unreliable and, once more, simply serves to inflate projected sales. *See Virgin*, 69 F. Supp. 2d at 579 ("expert testimony without . . . a factual foundation cannot defeat a motion for summary judgment"); *see also Lava Trading*, 2005 WL 4684238 at *16-17; *Celebrity*, 434 F. Supp. 2d at 181-86; *Point Prods.*, 2004 WL 345551 at *7.

- ***Years to Peak Market Share & Uptake Function***. Other critical assumptions in Mr. Slovick's model relate to the time he assumes it would have taken for Lemtrada to reach its peak in terms of total sales in the market. Mr. Slovick assumes [redacted] Venezia Decl. Ex. G at ¶¶ 240-41. (Slovick Rep.). As Mr. Slovick explained, [redacted] And, not surprisingly, their inclusion simply inflated Mr. Slovick's projected totals. *See Celebrity*, 434 F. Supp. 2d at 186 (excluding proposed expert testimony that relied on "projections that were not borne out of reality"; "[t]his defect drives the entire calculation and is not repaired by identifying a lower bound using a methodology which, standing alone, might be more reliable"); *Point Prods.*, 2004 WL 345551 at *7 (excluding proposed expert testimony regarding projected sales where the expert failed to account for "real world facts and events" and, instead, "adopt[ed] possibly speculative assumptions and predictions").

Put simply, the "multitude of assumptions" embedded in the Slovick Sales Model -- each of which "require[s] 'speculation and conjecture'" -- "do not provide the requisite certainty" to establish that there would have been $400 million in Lemtrada qualifying sales *but for* Sanofi's alleged conduct. *Schonfeld v. Hilliard*, 218 F.3d 164, 172 (2d. Cir. 2000); *see also, e.g.*, *Upper Deck*, 390 F. Supp. 2d at 360 (granting summary judgment where expert's "calculations [we]re based on too many unsupportable assumptions to establish the existence of lost royalties with the

reasonable certainty required"); *Franconero*, 2011 WL 566794 at *7 (granting summary judgment where the expert affidavit consisted of "conclusory statements" insufficient to establish causation).[17]

* * *

Once again, Plaintiff's theory of causation and damages lacks the requisite evidentiary support. The Slovick Sales Model cannot possibly establish the requisite causal link between any alleged breach by Sanofi and the failure to achieve PSM#1. Given the failings of the Slovick Sales Model, along with the lack of any other evidence available to Plaintiff regarding PSM#1 (in light of, among other things, Plaintiff's disclaimer of reliance on Sanofi's Product Sales Statements for Lemtrada), summary judgment should be granted on Count II.

IV. PLAINTIFF CANNOT ESTABLISH THAT, BUT FOR SANOFI'S ALLEGED CONDUCT, THE PRODUCTION MILESTONE WOULD HAVE BEEN ACHIEVED

In Count VII, Plaintiff claims that, "[a]s a result of Sanofi's [failure to use commercially reasonable efforts,] the Production Milestone was not met." Compl. ¶ 280. According to Plaintiff, with respect to Count VII, Sanofi owes damages to Plaintiff in the amount of $1 per CVR. *Id.* at p. 69, ¶ G. In order to recover on Count VII, and assuming solely for the purposes

[17] The Slovick Sales Model is made no more reliable by [redacted] Venezia Decl. Ex. G at ¶ 209 (Slovick Rep.). Mr. Slovick points to [redacted] *Id.* at ¶¶ 211-17. [redacted] Where a plaintiff must provide evidence of causation in connection with damages, "[a] defendant's own projections cannot satisfy the requisite level of certainty," particularly "in situations involving a new product with relatively little sales history." *Holland Loader*, 313 F. Supp. 3d at 481 (citations omitted); *Upper Deck*, 390 F. Supp. 2d at 360 n.1. That is precisely the case here.

Relatedly, Mr. Slovick also purports [redacted] Venezia Decl. Ex. G at ¶ 32 (Slovick Rep.); *see also* Venezia Decl. Ex. H at 184:15-22 (Slovick Tr.). MBE Associates, however, is not a financial firm, and the report relied on by Mr. Slovick was simply the end-result of student-generated work by three Rutgers MBA students, which Mr. Slovick conceded he did not completely vet before using it in his report. Venezia Decl. Ex. H at 187:5-188:21 (Slovick Tr.).

of this Motion that Plaintiff can establish the predicate failure by Sanofi to use commercially reasonable efforts, Plaintiff must establish that, *but for* Sanofi's alleged conduct, the Production Milestone would have been achieved. Plaintiff has not (and cannot) meet its burden.

The Production Milestone requires the production and Release (as defined in the CVR Agreement) of *both* 734,600 400 Unit VEs of Cerezyme *and* 79,000 35mg VEs of Fabrazyme by December 31, 2011. SOF ¶ 25. As of December 31, 2011, there was a shortfall of [redacted] 400 Unit VEs of Cerezyme and [redacted] 35mg VEs of Fabrazyme. Venezia Decl. Ex. I at ¶¶ 97, 113 (Phillips Rep.). Thus, in order to recover on Count VII, Plaintiff must prove that had Sanofi used commercially reasonable efforts, it would have caused the production and Release of: (i) an additional [redacted] 400 Unit VEs of Cerezyme; *and* (ii) an additional [redacted] 35mg VEs of Fabrazyme by December 31, 2011. Plaintiff cannot.

As with Counts I and II, Plaintiff attempts to satisfy its burden by relying on the opinions of two proposed experts: David Smolin and Dr. Janice Phillips. Both assert that [redacted] Venezia Decl. Ex. J at ¶¶ 42-43, 49-50, 52 (Smolin Rep.); Venezia Decl. Ex. I at ¶¶ 51-53, 65-66, 86 (Phillips Rep.). Both also assert that [redacted]. Venezia Decl. Ex. J at ¶¶ 65, 87 (Smolin Rep.); Venezia Decl. Ex. I at ¶¶ 54, 83-84 (Phillips Rep.). Dr. Phillips further asserts that, in her view, [redacted]. Venezia Decl. Ex. I at ¶¶ 97-112, 113-134 (Phillips Rep.).

Based on these assertions, both Mr. Smolin and Dr. Phillips leap to the conclusion that had these proposed actions been taken by Sanofi, the Production Milestone would have been achieved. What is missing, however, is *actual evidence* that: (i) the various actions identified by Plaintiff's proposed experts were actually feasible (from a technical and regulatory perspective); and (ii) even assuming such actions were feasible, and further assuming they were actually taken, that they would have impacted the production process in a manner sufficient to actually increase production yields of *both* Cerezyme and Fabrazyme at all, much less to the levels necessary to achieve the Production Milestone.[18] *See Virgin*, 69 F. Supp. 2d at 579 ("[w]hen an expert opinion is not supported by sufficient facts to validate it in the eyes of the law . . . it cannot support a jury's verdict"); *see also Lippe*, 288 B.R. at 686 ("expert testimony should be excluded if it is 'speculative or conjectural'").

A. Plaintiff Has No Evidence That, Had Sanofi Taken Certain Actions Earlier Than It Did, The Production Milestone Would Have Been Achieved

Both Mr. Smolin and Dr. Phillips assert that [redacted] Venezia Decl. Ex. J at ¶¶ 42-43, 49-50, 52 (Smolin Rep.); Venezia Decl. Ex. I at ¶¶ 51-53, 65-66, 86 (Phillips Rep.). These assertions are based, in large part, on Mr. Smolin's and Dr. Phillips' supposition that [redacted] Venezia Decl. Ex. J at ¶¶ 42-46 (Smolin Rep.); Venezia Decl. Ex. I at ¶¶ 51-52, 65-66 (Phillips Rep.). But, as both Mr.

[18] Sanofi's obligations under the CVR Agreement commenced no earlier than March 30, 2011, the date the CVR Agreement was actually signed and executed between Sanofi and its counter-party, American Stock Transfer & Trust Co., the predecessor trustee. Compl. ¶ 187 ("*The effective date of the CVR Agreement is March 30, 2011*. That is, all of the obligations of the CVR Agreement due by Sanofi commenced no later than March 30, 2011, the date of the execution by Sanofi.") (emphasis added).

Smolin and Dr. Phillips admitted, one does not have access to full and complete information during the course of acquisition due diligence, which is important given the complexity of the biomanufacturing process used to produce Cerezyme and Fabrazyme. Venezia Decl. Ex. K at 46:14-19 (Smolin Tr.); Venezia Decl. Ex. L at 102:11-13 (Phillips Tr.).

Regardless, the notion that Sanofi could have moved faster than it did given the complex biomanufacturing processes at issue -- and the additional hurdle of having to operate the Genzyme production facilities under a Consent Decree imposed by the FDA (SOF ¶ 28) -- has no support in the record and is based on nothing more than the say-so (based on conjecture and hindsight) of both Mr. Smolin and Dr. Phillips. *See Nimely*, 414 F.3d at 396 ("[n]othing . . . requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert"). Moreover, there is no way to measure -- without engaging in speculation -- what impact (if any) a different action plan would have had *more than eight years ago*. Indeed, the sole basis for Dr. Phillips' conclusion that [redacted]. Venezia Decl. Ex. I ¶¶ 86-96 (Phillips Rep.); Venezia Decl. Ex. L at 271:23-272:13, 274:22-275:24 (Phillips Tr.). This, however, cannot possibly be enough to establish that additional amounts of *both* Cerezyme *and* Fabrazyme would have been produced sufficient to achieve the Production Milestone by December 31, 2011, *but for* Sanofi's alleged conduct.

B. Plaintiff Has No Evidence That, Had Sanofi Implemented Additional Process Improvements, The Production Milestone Would Have Been Achieved

Dr. Phillips suggests that [redacted]. Venezia Decl. Ex. I at ¶¶ 83-84, 98-112, 113-34 (Phillips Rep.).

Mr. Smolin -- who admittedly is *not* an expert in the biomanufacturing technology used to produce Cerezyme and Fabrazyme (Venezia Decl. Ex. K at 94:5-14 (Smolin Tr.) -- [redacted] Venezia Decl. Ex. J at ¶¶ 65, 72 (Smolin Rep.).[19]

[19] The FDA has published regulations and guidance describing Chemistry, Manufacture & Control ("CMC") post-approval manufacturing changes that are applicable to drugs like Cerezyme and Fabrazyme. *See* 21 CFR 314.70 and 601.12; *see also* FDA Guidance for Industry: Changes to An Approved Application for Specified Biotechnology and Specified Synthetic Biological Products (July 1997); Manual of Policies and Procedures – Center for Drug Evaluation and Research (October 4, 2017). There are four different categories of regulatory notifications for CMC changes: (1) those requiring a Prior Approval Supplement ("PAS"); (2) those requiring a supplemental filing at least 30 days prior to product distribution ("CBE-30"); (3) those where the product may be distributed following submission of the supplement without waiting for approval ("CBE-0"); and (4) those believed to have a minimal

The conclusions reached by both Dr. Phillips and Mr. Smolin consist of pure conjecture and hypothetical contrivances (with the benefit of hindsight) some eight years after the events in question. *See Mirena*, 169 F. Supp. 3d at 466-67 (excluding expert testimony on what the FDA "would or would not have ultimately accepted or rejected" as "impermissible speculation as to the state of mind of the FDA"); *Rezulin*, 309 F. Supp. 2d at 546 (excluding expert testimony "on the intent, motives or states of mind of . . . regulatory agencies . . ." as "hav[ing] no basis in any relevant body of knowledge or expertise"); *Nimely*, 414 F.3d at 396 (similar). Neither Mr. Smolin nor Dr. Phillips bothered to analyze whether *any* of the proposed actions and technical process improvements were actually feasible and, even assuming they were, whether they could have been implemented in sufficient time to cause the Release of additional Cerezyme VEs and Fabrazyme VEs by December 31, 2011. *See* Venezia Decl. Ex. K at 217:12-18 (Smolin Tr.) ("Q. And with respect to the proposed process improvements that [Dr. Phillips] references in her report, have you performed any analyses on your own to determine whether each would have been feasible to implement at the relevant time? A. No, not -- not an analysis like that."); Venezia Decl. Ex. L at 287:4-288:12 (Phillips Tr.) ("Q. Okay. Did you analyze what the process would look like for each of these changes? A. I did not -- I did not do that detailed analysis of -- because, as I said, all right, I was dealing with the technical aspects of the process, okay, and not the other aspects of any one of these activities that would relate to regulatory issues."); *see also id.* at 287:13-288:3, 288:12-25 (Phillips Tr.).

Moreover, Dr. Phillips admitted that, even had these changes been put in place, it did not

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impact on product quality, known as "Minor Changes," which can be notified in an annual report for the product. *Id*. In short, a CMC change requiring a PAS takes the longest to implement while, at the other end of the spectrum, a CMC change that qualifies as a Minor Change can be implemented immediately. *Id.* A CMC change that can be accomplished via a CBE-0 can, in theory, also be implemented immediately upon submission of the required documentation to the FDA, but the applicant runs the risk of having to undo the change if approval ultimately is not obtained. *Id*.

follow that the Production Milestone would have been achieved. Venezia Decl. Ex. L at 332:14-25 (Phillips Tr.) ("Q: Okay. And just to make sure we are on the same page here, all of these things that you list in all of these bullets in paragraph 83 are things that should have been considered, not necessarily things that would have resulted in releases in 2011, not necessarily things that would have met the Production Milestone; right? A. Not -- not necessarily, because as we pointed out, okay, some of these may have required regulatory filings that would have extended past 2011."); *see also id.* at 318:16-24.

Indeed, notwithstanding Mr. Smolin's conclusion that [redacted] he later admitted that he could not state that the FDA would, in fact, take that approach. *See* Venezia Decl. Ex. K at 223:22-224:8 (Smolin Tr.) ("Q. Are you able to say with certainty that any of the process improvements that Ms. Phillips talks about in her report would have been accepted as a CBE-0 or a CBE-30? A. I can't say that with certainty, but I think there is an appropriate probability that they would have been accepted under a lower regulatory classification that should have been pursued by direct discussion with FDA, because, in my opinion, these don't constitute major changes."). Nor could Mr. Smolin recall a *single instance* in which, in the context of a post-approval change like those proposed by Plaintiff for Cerezyme and Fabrazyme, he ever submitted an approval on either a CBE-0 or CBE-30 basis. Venezia Decl. Ex. K at 112:17-21, 224:9-16 (Smolin Tr.).

C. Plaintiff Has No Evidence That Additional WIP Lots For Both Cerezyme And Fabrazyme Could Have Been Released In 2011

Cerezyme. Dr. Phillips contends, without any explanation or analysis, that [redacted] Venezia Decl. Ex. I at ¶ 97 (Phillips Rep.). At her deposition, however, Dr. Phillips could not articulate *any*

basis for concluding that *any* of these Cerezyme WIP lots -- much less *all* of them -- could have been Released in 2011. Venezia Decl. Ex. L at 358:21-359:13 (Phillips Tr.); *see also Vargas*, 514 F. Supp. 2d at 445 ("[t]he testimony of an expert who equivocates . . . need not be credited by the Court in resolving a motion for summary judgment"); *Virgin*, 69 F. Supp. 2d at 579 ("[w]hen an expert opinion is not supported by sufficient facts to validate it in the eyes of the law . . . it cannot support a jury's verdict").

Fabrazyme. Dr. Phillips similarly claims, without any explanation or analysis, that three categories of Fabrazyme WIP lots Released in 2012 could have been Released in 2011 and, collectively, would have satisfied the 27,138 35mg VEs Fabrazyme shortfall. Venezia Decl. Ex. I at ¶ 113 (Phillips Rep.). Again, however, there is *no* support for her conclusion that any -- much less all -- of these additional Fabrazyme WIP lots actually could have been Released in 2011. Simply guessing that additional drug product may have been Released earlier is not sufficient. *See Virgin*, 69 F. Supp. 2d at 580; *Nimely* 414 F.3d at 396.

* * *

In sum, conjecture and speculation of the sort offered by Plaintiff's experts here has been routinely rejected at the summary judgment stage for the purpose of establishing causation and damages. *See, e.g.*, *US Ecology*, 129 Cal. App. 4th at 910 (evidence did not show that it was "reasonably certain" that using contractually required "best efforts" would have caused the federal government to have acted differently); *Integrated Waste Servs., Inc.*, 921 F. Supp. at 1043 (because "the evidence is simply too sparse, and the contingencies too remote," any damage award "would be based on pure speculation"); *Semi-Tech Litig.*, 353 F. Supp. 2d at 486 (finding that plaintiff was not "entitled to have a jury fill [the evidentiary] gap by speculating as to how [plaintiff] might have behaved if [defendant] had acted differently"); *Upper Deck*, 390 F.

Supp. 2d at 361 ("[a]n expert's opinion is not a substitute for a plaintiff's obligation to provide evidence of facts"); *Schonfeld*, 218 F.3d at 172 (damages based on "'a multitude of assumptions' that require speculation and conjecture and few known factors do not provide the requisite certainty") (citation omitted). Summary judgment should therefore be granted on Count VII.

CONCLUSION

For the foregoing reasons, Sanofi's Motion with respect to each of Counts I, II, and VII should be granted.

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